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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/448,356

11/23/99

BURDICK

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20257/110665

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EXAMINER

QAZI, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/448,356

Applicant(s)

Burdick et al.

Examiner

Sabiha N. Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 5, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-23 is/are pending in the application.
- 4a) Of the above, claim(s) 9-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Final Action on Merits

Status of the Application

Claims 1-6 and 8-23 are pending.

Claims 1-6 and 8 are rejected.

Claim 7 is canceled.

Claims 9-23 are withdrawn from consideration as non elected invention. Restriction made FINAL.

Rejection Withdrawn

Claims 1-8 rejected under 35 U.S.C. 102(b) as being anticipated by Meittinen et al. (US Patent 5,502,045), lines 31-38, col. 4, lines 44-67, col. 4; claims 1, 5 and 6 and Eugster et al. (CA 120:245603 abstract of CH 681891) are withdrawn because claim 7 is canceled and other claims are amended.

Rejection Maintained

Claims rejected as being anticipated by WO 92/19640 lines 4-6, page 5; lines 8-37, page 6; Claims 1, 5 and 6 is maintained

Claims are amended but claims 1-7 are still considered anticipated, see lines 20-24, page 10; lines 22-30, page 9.

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Response to Arguments

Applicant's response has been fully considered but are not found persuasive. Following reasons apply.

2. Applicant's argue that due to priority the 102 rejections should be withdrawn. Note, that no priority documents are provided with this application which has been indicated in our first office action. All the rejections are maintained for the reasons set forth in our previous and other office actions.

1. Applicant elected group of compounds and composition claims 1-6 and 8 has been searched in this application. Other inventions must be canceled. No further groups will be searched. See MPEP 802.

The examiner has given the reasons as to distinctness of each invention, that search required for one group will not be the same for any other group and thus, a reference against one invention may not be applicable against the other invention. They are patentably distinct.

Instant invention is drawn to separate inventions which require separate searches, and are not art recognized

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equivalents. For example the search for the invention of group I would be different from the search for any other group.

Furthermore, a reference used to reject the invention of group I will not be used to reject the invention of group II.

Burden is likewise demonstrated by divergent classification and database search for the entire genus would represent excessive burden on the examiner.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. It would be an undue burden on the Examiner to search all the invention claimed in this application.

There are multiple inventions in one application and it would be a burden to examine all the invention in a proper way for the reasons cited above. For the same reasons restriction requirement is considered proper and restriction is made FINAL.

Claim 8 is improperly dependent on claim 1. Claim 8 does not further limit claim 8.

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1. Claim 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by Shimada et al. (JAOCS, Vol. 76, No. 6, (1999), pages 713-716).

See Table 3 on page 716 where esterification of sitosterol (which is a phytosterol) are disclosed. Fatty acid is the same as has claimed in amended claim 1, i.e. docosahexaenoic acid and eicosahexaenoic acid.

Claim(s) 1-6 and 8 are rejected under 35 U.S.C. 103 as being unpatentable Novak Egon WO 00/04887. See the entire document especially and lines 5-14 on page 10; last para on page 11; claims 1-11.

Novak Egon (WO 00/04887) teaches phytosterol and/or phytostanol esters compositions. The aliphatic acid may be selected from either straight chain of branched unsaturated or saturated fatty acids, (1st two lines of last para on page 11).

Instant claims differ from the reference in claiming specific fatty acids i.e. docosahexaenoic acid and eicosahexaenoic acid where as prior art teaches that aliphatic acid may be selected from either straight chain of branched

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unsaturated or saturated fatty acids. Instant claims are a selection of prior art teachings.

It would have been obvious to one skilled in the art to prepare additional beneficial composition by selecting specific docosahexaenoic acid and eicosahexaenoic acid from fatty acid taught by the prior art. There has been ample motivation provided by the prior art to prepare the instant invention by teaching unsaturated fatty acids and esters. Instant compositions would have been obvious at the time of invention.

The subject as instantly claimed would have been obvious to one at the time of invention.

It would have been obvious to prepare additional beneficial compositions as disclosed by the prior art.

Even if applicant's modification results in great improvement and utility over prior art, it may not be patentable if the modification was within the capabilities of one of the skilled in the art. More particularly, when the general conditions of the claim are disclosed by the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

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A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

The data showing any unexpected results would overcome the above 35 U.S.C. 103(a) rejection.

2. Claim(s) 1, 5, 6 and 8 are rejected under 35 U.S.C. 103 as being unpatentable over Miettinen et al. (WO 92/19640). See the entire document especially lines 22-30, page 9 and lines 20-24,

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page 10; lines 4-6, page 5; lines 8-37, page 6 in WO '640.

Miettenen et la. teaches a composition of β -sitostanol fatty acid ester or fatty acid ester mixture. The reference also teaches fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol. See claims 1-3.

Instant claims differ from the reference in claiming specific fatty acids i.e. docosahexaenoic acid and eicosahexaenoic acid where as prior art teaches fatty acids especially containing approximately 2-22 carbon atoms (lines 20-24, page 10). Instant claims are a selection of prior art teachings.

It would have been obvious to one skilled in the art to prepare additional beneficial composition by selecting any fatty acids for example, docosahexaenoic acid and eicosahexaenoic acid from fatty acid 2-22 carbon atoms taught by the prior art. There has been ample motivation provided by the prior art to prepare the instant invention. Instant compositions would have been obvious at the time of invention.

The subject as instantly claimed would have been obvious to one at the time of invention.

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It would have been obvious to prepare additional beneficial compositions as disclosed by the prior art.

Even if applicant's modification results in great improvement and utility over prior art, it may not be patentable if the modification was within the capabilities of one of the skilled in the art. More particularly, when the general conditions of the claim are disclosed by the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

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the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry Contacts


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can

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normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

5/11/001


SABIHA QAZI, PH.D
PRIMARY EXAMINER